ART Shielded Breast Applicator Premarket Notification

510k Summary of Safety and Effectiveness

ART Shielded Breast Applicator

NOV - 7 2006

1. Sponsor Name

Advanced Radiation Therapy, LLC
9 Linnell Circle, Billerica, MA 01821
Telephone: 978-663-7300
Fax 978-663-7322
Contact Individual: Raymond J. Bricault Jr., Chief Operating Officer

2. Device Name

ART Shielded Breast Applicator

3. Identification of Predicate or Legally Marketed Device

Advanced Radiation Therapy – ART Breast Brachytherapy Applicator –K060299
Mick Nuclear - HDR-IORT Shielded Applicator – K052351
Varian Medical Systems – Shielded Applicator Set – K033371

4. Device Description

The Advanced Radiation Therapy (ART) Shielded Breast Applicator is used for non-invasive HDR treatment of the breast. The applicator is designed to be positioned either external to a mammography style paddle which immobilizes the breast or directly against the breast with intact skin. Once the target has been immobilized and imaged the applicator is placed such that it is aligned with the target. The exterior shielding of the applicator will reduce dose to the surrounding tissue. The applicator is available in 5 sizes - 4, 5, 6, 7 and 8 cm ID.

5. Intended Use

The ART Shielded Breast Brachytherapy Applicator is intended for use with Nucletron or Varian remote afterloading systems for non-invasive brachytherapy in areas of intact skin.

6. Comparison of Technological Characteristics

The predicate devices and the ART Shielded Applicator are used to provide radiation to tissue via a remote afterloader device; all are intended as accessories to remote afterloaders.

7 Performance Testing

The Advanced Radiation Therapy Shielded Breast Applicator is a passive device. Performance testing was not required.

Statement of Equivalency

The ART Shielded Breast Applicator is substantially equivalent to the predicates, which provide the same or similar functions. The intended use, statement of indications, and technological and performance characteristics of the ART Shielded Breast Applicator support the concept of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Raymond J. Bricault Jr.
Chief Operating Officer
Advanced Radiation Therapy, LLC
9 Linnell Circle
BILLERICA MA 01821-3902

NOV - 7 2006

Re: K062135
Trade/Device Name: ART Shielded Breast Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: October 6, 2006
Received: October 10, 2006

Dear Mr. Bricault:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ART Shielded Breast Applicator Premarket Notification

Indications for Use

510(k) Number (if known): K062135

Device Name: ART Shielded Breast Applicator

Indications for Use:

The ART Shielded Breast Applicator is intended for use with Nucletron or Varian remote afterloading HDR equipment for non-invasive brachytherapy of the breast in areas of intact skin.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legassie

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062135